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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/600,094	08/22/2000	Henry Buchwald	12335.1USWO	8850

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EXAMINER

WALLENHORST, MAUREEN

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 01/07/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/600,094

Applicant(s)

BUCHWALD ET AL.

Examiner

Maureen M. Wallenhorst

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 and 28-56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25, 28-34, 36, 41, 42 and 55 is/are rejected.
- 7) ☒ Claim(s) 35, 37-40, 43-51 and 56 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>9</u> . | 6) <input type="checkbox"/> Other: _____ |

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1. Claims 15-23 and 55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

On lines 4, 12 and 20 of claim 15, the phrases “being configured to” and “configured to” are indefinite since the recitation that an element is “configured to” perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense.

Claims 16 and 18 are indefinite since these claims recite that the oxygen level detector is an oxygen electrode or a fluorometric detector. However, claim 15, from which claims 16 and 18 depend, now recites that the oxygen level detector comprises a light source, a filter and photopickups. It is unclear how the oxygen level detector can be an electrode or a fluorometric detector when claim 15 recites the same element of the apparatus to include optical components such as a light source, etc.

On the last line of claim 55, the phrase --measured at an earlier time-- should be inserted after the phrase “previous lipid level” so as to make it clear that the patient’s lipid level is measured at different points in time.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

3. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

4. Claims 1-14 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-14 of prior U.S. Patent No. 6,037,181. This is a double patenting rejection.

5. Claims 28-33 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-3 and 8-10 of copending Application No. 09/645,236. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 28-33 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 and 6-8 of U.S. Patent No. 6,037,181.

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Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-3 and 6-8 of US Patent no. 6,037,181 encompass a method for determining a patient's blood oxygen transport since these claims recite the same steps as claims 28-33 of the instant application, i.e. both sets of claims recite the steps of obtaining a blood sample from a patient and measuring the rate of oxygen diffusion across a membrane of a red blood cell in the blood sample.

8. Claims 1-2, 15-19, 23-25, 34 and 42 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 12, 15-18, 24, 34-36, 39-40 and 48-53 of copending Application No. 09/645,236. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims recite a method for determining a patient's susceptibility to angina by obtaining a blood sample from a patient, measuring a rate of oxygen diffusion across a membrane of a red blood cell of the blood sample, and correlating the measured rate with a susceptibility to angina in a control population or in the patient at the measured rate, as well as correlating the measured rate with conditions of the patient under stress such as a cardiac stress test. In addition, both sets of claims recite an apparatus for measuring the diffusion of oxygen across a red blood cell membrane comprising an oxygen level detector, a gas exchange system and a red blood cell transport system, wherein the red blood cell transport system comprises a pump to transport a red blood cell to the gas exchange system, the gas exchange system comprises a gas permeable tubing in a housing for diffusing gas from the housing to a red blood cell contained in the tubing, and the oxygen level detector is one of an oxygen electrode, a spectrophotometric detector or a fluorometric detector.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 15, 17, 19, 22-23, 36 and 41-42 are rejected under 35 U.S.C. 102(b) as being anticipated by Page et al. (from Chapter 9- Exp. Simulation of Oxygen Transport in Microvessels cited in the Information Disclosure Statement filed December 29, 2000).

Page et al. teach of an apparatus for measuring diffusion of oxygen across a red blood cell membrane, which comprises a microflow system that serves as a red blood cell transport system, an oxygen level detector and a gas exchange system. The gas exchange system comprises a capillary imbedded in a thin film of silicone rubber. Test blood samples are held in a reservoir and withdrawn by a syringe pump that acts as the red blood cell transport system into the capillary lumen where gas exchange occurs. In an oxygen uptake experiment, both surfaces of the capillary are exposed to humidified air and a fully deoxygenated sample is oxygenated as it flows through the lumen of the capillary. In an oxygen release experiment, both surfaces of the capillary are exposed to humidified nitrogen and a fully saturated blood sample is deoxygenated as it flows through the lumen of the capillary. A shroud surrounds the capillary and serves as a housing that holds the desired oxygen atmosphere around the capillary. The shroud has windows at the top and bottom to allow the passage of light. The oxygen level detector comprises a microspectrophotometer which makes absorbance measurements at various axial positions along the capillary. A data acquisition and control system controls the axial positioning of the apparatus and the logging of absorbance and other data.

It appears that this reference to Page et al. was published in 1996 since the other Page et al. article cited in the Information Disclosure Statement dated 12-29-00 (from Microvascular Research) indicates that this Page et al. reference, in the lower right hand corner of page 55, was published in 1996.

11. Claims 28-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Runck et al (US Patent no. 3,779,708, cited in the Information Disclosure Statement filed on September 16, 2002).

Runck et al teach of a method for measuring the rate of oxygen diffusion across the membrane of a red blood cell in a blood sample of a patient. In one embodiment, blood oxygen transport is measured by introducing a blood sample from a patient through a line 11 into a tube 13 where deoxygenation occurs by introducing a gas sample of nitrogen to the blood. The oxygen free blood is then flowed through line 16 to an oxygenation tube 19 where oxygen at known concentrations is mixed with the blood. The blood is then tested at 22 to measure the amount of oxygen that was transported across the red blood cell membranes, and the rate of oxygen diffusion into the blood cells. See Figure 1 in Runck et al. The process can be reversed in the embodiment depicted in Figure 2 of Runck et al where the blood is first exposed to oxygen before being exposed to an environment depleted of oxygen.

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. Claims ~~16~~, 18, 20-21 and ~~52-54~~ are rejected under 35 U.S.C. 103(a) as being unpatentable over Page et al. in view of Applicants' admitted prior art. For a teaching of Page et al. (from Chapter 9- Exp. Simulation of Oxygen Transport in Microvessels cited in the Information Disclosure Statement filed December 29, 2000), see previous paragraphs in this Office action. Page et al. fail to teach that the oxygen level detector can be an oxygen electrode or a fluorometric detector.

Applicants admit on lines 1-10 of page 5 in the instant specification that oxygen levels in blood are known in the art to be measured by spectrophotometric methods, fluorometric methods and potentiometric methods utilizing oxygen electrodes. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to use an oxygen electrode or a fluorometric detector in place of the spectrophotometric detector taught by Page et al. as the oxygen level detector since these are both known prior art methods of measuring oxygen levels in blood equivalent in function to a spectrophotometric detector.

It also would have been obvious to one of ordinary skill in the art to use a peristaltic pump or an aspirator in place of the syringe pump taught by Page et al. for transporting a red blood cell sample to the capillary gas exchange system in the apparatus of Page et al. since peristaltic pumps and aspirators are known in the art to perform the equivalent functions of a syringe pump for injecting and transporting fluid samples. It also would have been obvious to one of ordinary skill in the art to provide the control system taught by Page et al with a display,

printer and data retention apparatus so as to convey the results of the oxygen transport analysis performed with the apparatus to a user of the system.

15. Claims 35, 37-40, 43-51 and 56 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

16. Applicant's arguments filed October 24, 2002 have been fully considered but they are not persuasive.

The previous rejections of the claims made under 35 USC 112, second paragraph in the last Office action dated July 18, 2002 have been withdrawn as necessitated by Applicants' amendments to the claims. However, new rejections of the amended claims under this statute are set forth above. Amended claim 15 still contains the language "being configured to" which was rejected in the previous Office action as not being a positive limitation.

Claims 1-14 are still rejected under 35 USC 101 as claiming the same invention as claims 1-14 of US Patent no. 6,037,181 since claim 1, as amended, includes an embodiment where the measured rate of oxygen diffusion is correlated with only established levels of blood lipid to determine a patient's blood lipid level, which is the same as what is recited in claims 1-14 of US patent no. 6,037,181. Claim 1, as amended, recites that the measured rate of oxygen diffusion can be correlated to one of three things or "a combination thereof", which means that the measured oxygen diffusion can be correlated to any combination of one, two or three of the recited levels, thus including the correlation to only established levels of blood lipid to determine a patient's blood lipid level.

The rejection of claims 28-33 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 and 6-8 of US patent no. 6,037,181 is maintained since an appropriate terminal disclaimer has not yet been filed by Applicants.

Claims 28-30 and 31-33 are newly provisionally rejected under 35 USC 101 as claiming the same invention as claims 1-3 and 8-10 of application serial no. 09/645,236. In addition, claims 1-2, 15-19, 23-25, 34 and 42 are newly provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 12, 15-18, 24, 34-36, 39-40 and 48-53 of application serial no. 09/645,235 for the reasons set forth above. This Office action is being made non-final because of these new grounds of rejection.

Applicants argue the rejection of the claims under 35 USC 102 and 35 USC 103 as being anticipated and obvious over Page et al by stating that Page et al does not disclose a system having both a sample receiving system and a gas exchange system since gas exchange occurs in the feed reservoir. Therefore, Applicants argue that the feed reservoir in Page et al serves as both the sample receiving system and the gas exchange system. In addition, Applicants argue that Page et al fail to teach of a gas permeable tubing located within the housing or shroud for diffusing gases from the gas exchange chamber to a red blood cell contained within the gas permeable tubing. In response to these arguments, it is noted that Page et al also teach that gas exchange occurs between the capillary, surrounded by oxygen permeable silicone rubber, and the shroud in which the capillary is located, in addition to the gas exchange which occurs in the feed reservoir. Page et al teach that in an oxygen saturation measurement, humidified nitrogen suffuses the external capillary space to maintain zero saturation level. A blood sample containing red blood cells is then drawn from the feed reservoir to the capillary by a syringe

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pump. The nitrogen suffusing the extracapillary space in the shroud is then replaced by humidified air. This creates an uptake experiment where oxygen is taken up by the red blood cells of the sample as it passes down the capillary. Therefore, oxygen does diffuse across the permeable capillary wall into the blood sample held by the capillary, and gas exchange does take place in the shroud chamber holding the capillary of Page et al, contrary to Applicants' argument. See section 9.3.3 on page 138 of the Page et al article. Therefore, in the apparatus depicted in Figure 9.1 of Page et al, the feed reservoir can be considered a sample receiving system, and the shroud containing the gas permeable capillary can be considered the gas exchange system.

For all of the above reasons, Applicants' arguments are not found persuasive.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is (703) 308-3912. The examiner can normally be reached on Monday-Wednesday from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on (703) 308-4037. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-7719.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

mmw
January 6, 2003

Maureen M. Wallenhorst
MAUREEN M. WALLENHORST
PRIMARY EXAMINER
GROUP 100